UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/373,984	08/16/99	SU X	70862/93137

HM22/1010

MCKENNA & CUNEO, L.L.P.
1900 K STREET, NW
WASHINGTON DC 20006

EXAMINER	
TUNG, J	

ART UNIT	PAPER NUMBER
1656	17

DATE MAILED: 10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/373,984	Su et al.
Examiner	**Art Unit**
Joyce Tung	1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 7/27/01 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 3-13, and 20-25 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 3-13, 20-25 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 16

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 7/27/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/373, 984 is acceptable and a CPA has been established. An action on the CPA follows.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper tames extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.d. 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 5-8 and 10-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17, 24-43 and 50-69 of copending Application No. 09/285,658. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 5-8 and 10-22 are drawn the method which is included in the claims 1-17, 24-43 and 50-69 of copending Application No.

09/285,658 in which claims 1-17, 24-43 and 50-69 are drawn to a method of proportional amplification of nucleic acid comprising creating fragments of a single-stranded DNA population, synthesizing double-stranded DNA from the fragment of the single stranded DNA population and producing multiple copies of sense RNA from the double-stranded DNA, the amplified DNA is detected. Thus, this is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3-13 and 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1, 3-13 and 20-25 are vague and indefinite under 35 U.S.C. 112, second paragraph because the language "said amplification is proportional" is unclear how the language is defined in the specification.

Claim Rejections - 35 U.S.C. § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3-7 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sooknanan et al. (WO 96.17079).

Sooknanan et al. disclose terminal repeat amplification method in which the method provides a single medium comprising RNA polymerase, DNA polymerase and RNAse (See the Abstract) and ligase (See pg. 8, first paragraph) (As recited in claims 1 and 25). The method produces double stranded DNA and then produce multiple copies of RNA from double stranded DNA (See the Abstract). The method also involves membrane as recited in claims 6 and 7 and a labeled probes (This indicates that the method will be used for detection as recited in claim 6). Sooknanan et al. disclose a kit containing the reagents of the methods (See the Abstract) (As recited in claims 22-24). Thus the teachings of Sooknanan et al. anticipate the limitations of claims 1, 3-7 and 25.

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sooknanan et al. (WO 96.17079) as applied to claims 1 and 3-7 above, and further in view of Kwoh et al. (Proc. Natl. Acad. Sci. USA, 1989, Vol. 86, pg. 1173-1177) and Goller et al. (Oncogene, 1998, Vol. 16, pg. 2945-2948).

The limitations of instant claim 1 are rejected under 35 U.S.C. 102(b) anticipated by the teachings of Sooknanan et al. set forth in section 7 above.

Sooknanan et al. do not disclose that the nucleic acid is isolated from the cell or tissues as recited in claims 8-13.

Kwoh et al. disclose a method of amplifying RNA involving a double stranded cDNA synthesis and then the cDNA is used as template to produce multiple copies of RNA (See pg. 1171, the Abstract). The target nucleic acid can be total RNA (See pg. 1173, column 2, fifth

paragraph) or DNA (See pg. 1173, the Abstract). The total RNA inherits that there is mRNA included. The amplified products are detected with the use of a slot-blot apparatus comprising nucleic acid probes (See pg. 1174, column 1, second paragraph). The amplified products are also detected by sephacryl beads containing nucleic acid probes (See pg. 1174, column 1, third paragraph). Since the total RNA is from HIV-1-infected lymphocyte cells, this indicates that the infected cells must be eukaryotic cell. The cells must also be human cells which are mammalian cell. Based upon the description of the procedure of amplifying RNA, there is no indication that an extraction or precipitation occurred during the procedure) (See pg. 1174, second paragraph). This is the same as the indication in the specification that the reaction can occur in one phase which is without organic extracting and precipitation (See pg 5, lines 25-28).

Goller et al. disclose the analysis of differential gene expression in v-jun-transformed chicken embryo fibroblasts (CEF) compared to normal CEF by using tag PCR subtraction method (See the Abstract). The target is from mRNA of CEF (See pg. 2946, fig. 2) (as recited in claim 13).

One of ordinary skill in the art at the time of the instant invention would have been motivated to use RNA from eukaryotic cell or tissues as recited in claims 8-12 in the method of Sooknanan et al. because the expression of the glutaredoxin mRNA could be induced by a jun-estrogen receptor chimaera in the absence of *de novo* protein biosynthesis and therefore the oncogene can be studied (See the Abstract) and the tissues used in the method of Kwoh et al.

does not affect the specificity of the method (See pg. 1173, the Abstract). It would have been prima facie obvious to carry out the method as claimed.

10. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sooknanan et al. (WO 96.17079) as applied to claims 1 and 3-7 above, and further in view of Schnipelsky et al. (5,229,297).

The limitations of instant claim 1 are rejected under 35 U.S.C. 102(b) anticipated by the teachings of Sooknanan et al. set forth in section 7 above.

Sooknanan et al. do not disclose the method which is involved using an automated machine.

Schnipelsky et al. disclose an apparatus to amplify a nucleic acid sequence (See column 2, lines 17-24). The apparatus involves PCR thermocycler (See column 14, lines 7-9), an integrated reaction device and a robotic delivery system (See column 9, lines 26-60).

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the apparatus of Schnipelsky et al. to the method of Sooknanan et al. because the apparatus of Schnipelsky et al. can prevent sample from contamination (See column 2, lines 17-24). It would have prima facie obvious to carry out the method as claimed.

11. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

October 6, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
10/9/01